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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
09/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	09/809,029	BARNARDO ET AL.	
	Examiner	Art Unit	
	GARY W. COUNTS	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,11-17,20,22,24-27,and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,11-17,20,22,24-27 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

The amendment filed July 1, 2008 is acknowledged and has been entered. Currently, claims 1-7, 11-17, 20, 22, 24-27 and 29 are pending and under examination.

Rejections Withdrawn

In light of Applicant's arguments filed July 1, 2008 that the Frayser and Arimilli references successfully prepared MHC Class II monomers and that there would not be a low level of predictability in making MHC class II monomers, the 112 first enablement rejection of claims 1-7, 11-17, 20, 22, 24-27 and 29 are hereby, withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-7, 13, 16 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Barnardo et al (Detection of HLA antibodies using single recombinant HLA alleles, Human Immunology, Abstracts 1999, Volume 60, Supplement 2).

Barnardo et al., disclose a method of detecting allele specific HLA antibodies in a sample from a patient. Barnardo et al disclose biotinylated recombinant HLA molecules immobilized to a streptavidin-coated microtitre plate (7.4, p. S9). Barnardo et al disclose the recombinant molecules are biotinylated monomer preparations (HLA-

A*0201 and HLA-B*0801), presenting an HIV-Gag and an HCV peptide (same monomer preparations as disclosed by applicant). Barnardo et al disclose contacting patient sera (body fluid) with the immobilized recombinant HLA molecules and detecting the binding of antibodies to the immobilized recombinant HLA molecules with detection antibodies such as anti-human IgG-HRP conjugate. Barnardo et al disclose the assay can be an ELISA assay.

It is noted that the above reference Barnardo et al has common authors which are listed as inventors in the current application. It is also noted that the above reference is considered prior art because it is considered to be by others, because the reference lists Olivia Shaw and Graham Ogg as authors and Shaw and Ogg are not listed as inventors of the current application. Therefore, it is considered to be by others.

3. Claims 1-7, 11, 13, 16 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Barnardo et al (Detection of HLA-Specific IgG using single, recombinant HLA alleles, Human Immunology (1999) Vol 60., No. Suppl. 1, pp. S1).

Barnardo et al disclose a method of detecting HLA-specific IgG using recombinant HLA molecules (p. S1). Barnardo et al disclose biotinylated recombinant HLA molecules immobilized to a strptavidin-coated microspheres. Barnardo et al also disclose that the molecules could be immobilized to ELISA plates. Barnardo et al disclose that the monomer preparation is HLA-A*0201 (same monomer preparation as disclosed by applicant). Barnardo et al disclose that antibody binding to the beads was measured by anti-human IgG-FITC conjugate.

It is noted that the above reference Barnardo et al has common authors which are listed as inventors in the current application. It is also noted that the above reference is considered prior art because it is considered to be by others, because the reference lists Graham Ogg as an author Ogg is not listed as an inventor of the current application. Therefore, it is considered to be by others.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-7 and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (US 5,948,627) in view Chang et al (US 5,270,169) and further in view of Walter et al (International Immunology, Vol. 9, No. 3, p.451-459, 1997).

Lee et al disclose a method for detection of HLA antibodies. Lee et al disclose adding serum from a patient to microbeads, each microbead having immobilized HLA antigens. Lee et al disclose incubating the serum and microbeads for sufficient time for anti-HLA antibodies to bind to the HLA antigens. Lee et al also disclose the addition of a labeled ligand capable of specifically binding with anti-HLA antibodies bound to the HLA antigens and detecting the presence of labeled ligand bound to the HLA antigens.

Lee et al fail to teach the use of recombinant MHC or HLA molecules.

Chang et al teaches that it is known in the art that synthetic HLA antigens which mimic the antigenic reactivity of HLA epitopes are equivalent to HLA antigens for the detection of specific antibodies in a biological sample (col 3, lines 48-62). Chang et al teaches that the detection of the antibodies can be of antibodies to at least one HLA allele (col 2, lines 15-20). Chang et al also teaches HLA molecules can be attached to solid supports such as a microtiter plate, beads or nitrocellulose (col 3, lines 1-19).

Walter et al discloses that recombinant HLA molecules can be used to detect antibodies in a sample. Walter et al., disclose detecting a monoclonal PA2.1 antibodies (specific for HLA-A2 and A28). Walter et al disclose that this antibody binds to recombinant HLA-A2 peptide complexes. Walter et al disclose detecting the PA2.1

antibodies bound to the A2 complex with goat anti-mouse Ig conjugated to horseradish peroxidase (p. 452). Walter et al disclose that the HLA-A2 molecule is produced in E.Coli (prokaryotic expression system) (p. 451). Walter et al disclose the recombinant molecule can be immobilized and bound by antibody (p. 456, first column, lines 43 – 53). Walter et al disclose assembling the HLA-A2 (HLA-A*001) heavy chain and B_2-microglobuling in the presence of a peptide from gag protein (Gag, amino acids 77086, SLYNTVATL) (It is noted that this recombinant molecule appears to be the same recombinant molecule as disclosed by applicant (see page 23, Table 1). Walter et al disclose labeled antibodies that bind to the PA2.1 antibodies. Walter et al teaches that the recombinant complexes contain native epitopes, consistent with the presence of correctly folded molecular complexes (p.456, 2nd col).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a recombinant HLA antigen and the corresponding reagents as taught by Walter et al into the modified method of Lee et al because Chang et al teaches that it is known in the art of detecting HLA antibodies that a synthetic HLA antigen can be substituted as an equivalent reagent for HLA antigens for the purpose of detecting HLA antibodies and Walter shows that recombinant HLA antigens can be used to detect allele specific antibodies and that the recombinant complexes contain native epitopes, consistent with the presence of correctly folded molecular complexes. Therefore, one of ordinary skill would have a reasonable expectation of success substituting recombinant HLA antigens as taught by Walter et al into the modified method of Lee et al.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barnardo et al (Supplement 2) or Barnardo et al (Suppl. 1, pp. S1) in view of Pouletty et al (US 5,292,641.

See above for teachings of Barnardo et al (Supplement 2) and Barnardo et al (Suppl. 1, pp. S1).

Barnardo et al (Supplement 2) and Barnardo et al (Suppl. 1, pp. S1) differ from the instant invention in failing to teach the solid support is nitrocellulose.

Pouletty et al disclose HLA antigens which are immobilized to a nitrocellulose support (col 3, lines 22-54). Pouletty et al disclose that this immobilization of the HLA antigen provides a simple rapid and accurate method for the determination of the presence of antibodies to at least one HLA allele (col 2, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the use of a nitrocellulose support as taught by Pouletty et al into the method of Barnardo et al because Pouletty et al shows that this immobilization provides for a simple rapid and accurate method for the determination of the presence of antibodies to at least one HLA allele.

9. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnardo et al (Supplement 2) or Barnardo et al (Suppl. 1, pp. S1)in view of Baserga et al (US 6,218,363).

See above for teachings of Barnardo et al (Supplement 2) and Barnardo et al (Suppl. 1, pp. S1)

Barnardo et al (Supplement 2) and Barnardo et al (Suppl. 1, pp. S1) is silent with respect to the recombinant HLA being synthesized in a prokaryotic expression system.

Baserga et al also disclose that MHC or HLA Class I molecules can be produced by recombinant DNA techniques. Baserga et al disclose that the recombinant MHC or HLA Class I molecule is produced in the host by expression. The transformed host may be a prokaryotic or eukaryotic cell. (col 14, lines 1-21). These recombinant molecules retain the therapeutic or diagnostic activity of the naturally occurring molecule and provides methods of identifying MHC Class I peptides.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to synthesize the recombinant HLA as taught by Baserga et al for the method of Barnardo et al (Supplement 2) or Barnardo et al (Suppl. 1, pp. S1) because Baserga et al shows that these recombinant molecules retain the therapeutic or diagnostic activity of the naturally occurring molecule and provides methods of identifying MHC Class I peptides.

10. Claims 20, 22, 24-27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnardo et al (Detection of HLA antibodies using single recombinant HLA alleles, Human Immunology, Abstracts 1999, Volume 60, Supplement 2) or Barnardo et al (Detection of HLA-Specific IgG using single, recombinant HLA alleles, Human Immunology (1999) Vol 60., No. Suppl. 1, pp. S1) in view of Boguslaski (US 5,420,016).

See above for the teachings of Barnardo et al (Supplement 2) and Barnardo et al (Suppl. 1, pp. S1).

Barnardo et al (Supplement 2) and Barnardo et al (Suppl. 1, pp. S1) differ from the instant invention in failing to teach packaging the components into a kit.

Boguslaski et al disclose assembling various system components into a test kit. By assembling these components into test kits, it makes it more convenient and facile for the test operator (col 7, lines 8-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to assemble the various components of the method of Barnardo et al into kits such as taught by Boguslaski et al because Boguslaski shows that test kits make it more convenient and facile for the test operator.

11. Claims 20, 22, 24 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al., Chang et al and Walter et al as applied to claims 1-7, 11-17 above, and further in view of Boguslaski (US 5,420,016).

See above for the teachings of Lee et al., Chang et al and Walter et al.

Lee et al., Chang et al and Walter et al differ from the instant invention in failing to teach packaging the components into a kit.

Boguslaski et al disclose assembling various system components into a test kit. By assembling these components into test kits, it makes it more convenient and facile for the test operator (col 7, lines 8-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to assemble the various components of the modified method of Lee et al into kits such as taught by Boguslaski et al because Boguslaski shows that test kits make it more convenient and facile for the test operator.

12. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al., Chang et al., Walter et al and Boguslaski et al as applied to claims 1-7, 11-17, 20, 22, 24 and 29 above, and further in view of Luxembourg et al (US 2004/0137617).

See above for teachings of Lee et al., Chang et al., Walter et al and Boguslaski et al..

Lee et al., Chang et al Walter et al and Boguslaski et al differ from the instant invention in failing to teach the MHC or HLA molecule is fused to biotin.

Luxembourg et al disclose recombinant MHC molecules which are biotinylated (page 3, paragraph 0018, & page 4, paragraph 0027). Luxembourg et al disclose that these recombinant MHC molecules are biotinlyated to provide attachment to solid support coated with avidin. Luxemburg et al disclose that the use of this avidin-biotin system provides for the isolation of peptides such as antibodies (p. 5, paragraphs 0030, and 0031).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an avidin-biotin system as taught by Luxembourg et al into the modified method of Lee et al because Luxembourg et al shows that the use of this avidin-biotin system provides for the isolation of peptides such as antibodies. Further, the use of avidin-biotin systems to immobilize and capture reagents is very well known in the art. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating avidin-biotin as taught by Luxembourg et al into the modified method of Lee et al.

Response to Arguments

13. Applicant's arguments filed July 1, 2008 have been fully considered but they are not persuasive.

Rejections under 35 U.S.C. 102(a)

Applicant argues that the reference Barnardo et al. (Detection of HLA antibodies using single recombinant HLA alleles, Human Immunology, Abstracts 1999, Vol 60, Suppl. 2) is not "by others". Applicant states that as stated in point 2 of Dr. Bunce's declaration, Graham Ogg merely provided HLA class I monomers. As stated at point 3 of Dr. Bunce's declaration, Olivia Shaw merely carried out technical work under the direction of Andrea Harmer and as stated at point 4 of Dr. Bunce's declaration, neither Graham Ogg nor Olivia Shaw made any inventive contribution to the methods claimed in this application. This is not found persuasive because the Examiner did not find a declaration by Dr. Bunce making the statements that applicant is referring to. There, was no declaration submitted with the amendment filed July 1, 2008. The only declaration that the Examiner could find during prosecution was a declaration under Rule 132 submitted by Michael Bunce, submitted January 16, 2003 which was directed to an entirely different rejection based on the reference Ogg et al (Detection of HLA-specific IgG using single recombinant HLA alleles, abstract participants of British Transplantation 2nd Annual congress, 29-31, March 1999. A review of the Bunce declaration submitted January 16, 2003 does indicate that Graham Ogg made no inventive contribution to the invention but makes no reference to Olivia Shaw. Regardless, as stated above there was no declaration received directed to the current

rejection based on the reference Barnardo et al. (Detection of HLA antibodies using single recombinant HLA alleles, Human Immunology, Abstracts 1999, Vol 60, Suppl. 2). Therefore, the rejection is maintained.

Applicant also argues that the reference of Barnardo et al. (Detection of HLA antibodies using single recombinant HLA alleles, Human Immunology, Abstracts 1999, Vol. 60, No. Suppl. 1, pp. S1) is not "by others" and is therefore not prior art. Applicant states that as stated in point 2 of Dr. Bunce's declaration, Graham Ogg merely provided HLA class I monomers and as stated at point 4 of Dr. Bunce's declaration, Graham did not make any inventive contribution to the methods claimed in this application. This is not found persuasive because the Examiner did not find a declaration by Dr. Bunce making the statements that applicant is referring to. There, was no declaration submitted with the amendment filed July 1, 2008. The only declaration that the Examiner could find during prosecution was a declaration under Rule 132 submitted by Michael Bunce, submitted January 16, 2003 which was directed to an entirely different rejection based on the reference Ogg et al (Detection of HLA-specific IgG using single recombinant HLA alleles, abstract participants of British Transplantation 2nd Annual congress, 29-31, March 1999. A review of the Bunce declaration submitted January 16, 2003 does indicate that Graham Ogg made no inventive contribution to the invention. However, even if this were considered it would not overcome the rejection because the current application also lists Michael Bunce as an inventor and Michael Bunce is not listed as a coauthor of the reference (Detection of HLA antibodies using single recombinant HLA alleles, Human Immunology, Abstracts 1999, Vol. 60, No. Suppl. 1,

pp. S1) and therefore the inventors of the current application do not match up with the authors of the reference (Detection of HLA antibodies using single recombinant HLA alleles, Human Immunology, Abstracts 1999, Vol. 60, No. Suppl. 1, pp. S1) and thus would still be considered to be “by others” and would be prior art. Regardless, as stated above there was no declaration received directed to the current rejection based on the reference Barnardo et al. (Detection of HLA antibodies using single recombinant HLA alleles, Human Immunology, Abstracts 1999, Vol. 60, No. Suppl. 1, pp. S1). Thus, for the reasons stated above the rejection is maintained.

Rejections Under 35 U.S.C. 103(a)

Applicant argues that the pending independent claims (1, 2, and 20) of the application relate to methods (claims 1 and 2) or kits (claim 20) for detecting anti-MHC antibodies (such as anti-HLA antibodies) in a body fluid sample. Applicant states that immobilized recombinant MHC molecules (such as recombinant HLA molecules) that each bind to a different allele specific MHC antibody" are used to detect that Binding of antibodies specific to a particular MHC molecule. Thus the assay indicates to which particular type of MHC molecule an antibody in the body fluid sample binds and that this is neither demonstrated nor suggested by any of the cited references, and cannot be properly derived from a combination thereof. This is not found persuasive because the claim as recited only requires one immobilized recombinant MHC molecule which would bind to an allele specific antibody and the current combination of references clearly read on this limitation and one of ordinary skill would understand that an antibody which

would bind to the recombinant HLA molecule in the modified method of Lee would be an allele specific antibody.

14. Applicant further argues that Lee and Chang do not disclose the use of recombinant MHC class I or class II molecules, and do not show the skilled artisan how to detect antibodies with specificity for a particular recombinant MHC molecule. Applicant states that Chang does not specify which HLA antigens are being utilized in the assays and one of skilled in the art would not understand Chang to be using a particular HLA antigen but rather whichever HLA molecules are expressed by the undefined "lymphoblastoid cell line" and thus neither of these reference disclose the claimed method or kits. Applicant argues that Walter does not satisfy the deficiencies of Lee and Chang and particularly states that Walter does not disclose recombinant HLA molecules can be used to detect antibodies in a sample and that Walter does not show the detection of monoclonal PA2.1 antibodies from a body fluid sample. This is not found persuasive because the Examiner has not relied upon Walter et al for teaching the detection of antibodies in a body fluid sample but rather has relied upon Lee for teaching detecting the antibodies in a body fluid and also that Chang teaches the detection of antibodies in biological fluids and that the detection of the antibodies can be of antibodies to at least one HLA allele The Examiner has relied upon Walter for teaching that it is known in the art that antibodies can be detected in a sample using recombinant MHC molecules and has stated that it would have been obvious to substitute a recombinant HLA antigen and the corresponding reagents as taught by Walter et al for the synthetic HLA antigens in the modified method of Lee et al. Thus, it

appears that the applicant is arguing the references individually. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that the rejection of claim 12 over either Barnardo reference in view of Pouletti is improper because neither Barnardo reference is available as prior art. This is not found persuasive because of reasons stated above that the Barnardo references are prior art.

Applicant argues that the rejections of claims 14 and 15 over either Barnardo reference in view of Baserga et al is improper because neither Barnardo reference is available as prior art. This is not found persuasive because of reasons stated above that the Barnardo references are prior art.

Applicant argues that the rejections of claims 20, 22, 24-27 and 29 over either Barnardo reference in view of Boguslaski et al is improper because neither Barnardo reference is available as prior art. This is not found persuasive because of reasons stated above that the Barnardo references are prior art.

Applicant argues that a *prima facie* case of obviousness of the pending claims with respect to Lee, Chang and Walter has not been established and that the references of Boguslasi and Luxemborg do not satisfy the deficiencies of Lee, Chang and Walter. This is not found persuasive because of reasons stated above directed to Lee, Chang

and Walter as being obvious and thus the combination of the references Boguslaski and Luxemborg is considered appropriate and therefore maintained.

Conclusion

15. No claims are allowed.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/Mark L. Shibuya, Ph.D./
Supervisory Patent Examiner, Art Unit 1641